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Attachment IV

510(K) Summary of Safety and Effectiveness K003886

This 510(K) Summary of Safety and Effectiveness for the Palomar SpaLight™ Pulsed Light System is submitted in accordance with the requirements of Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(K) summary.

Applicant:	Palomar Medical Technologies, Inc.
Address:	82 Cambridge St. Burlington, MA 01803 781-993-2300
Contact Person:	Marcy Moore
Telephone:	919-363-2432
Preparation Date:	December 4, 2000
Device Trade Name:	Palomar SpaLight™
Common Name:	SpaLight™
Classification Name:	Laser surgical instrument for use in General and Plastic Surgery and in Dermatology (see: 21 CFR 878-4810). Product Code: GEX Panel: 79
Legally-Marketed Predicate Device:	Radiancy SpaTouch System K992482 ESC EpiLight K963249; K994014
System Description:	The SpaLight™ is a light-based medical device designed for effective removal of unwanted hair and treatment of facial and leg veins.
Intended Use of the Device:	The SpaLight™ System is intended to remove hair in Dermatology and Plastic Surgery procedures. It is also intended for Photocoagulation of dermatological vascular lesions, facial and leg veins.

Performance Data:	The differences in the specifications of the SpaLight™ and the predicate devices do not result in different performance or raise new questions of safety or efficacy.
Conclusion:	Based on the foregoing, the SpaLight™ System is substantially equivalent to the legally-marketed claimed predicate devices, i.e., the SpaTouch™ and EpiLight for hair removal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2001

Ms. Marcy Moore
Manager of Clinical Studies
Palomar Medical Technologies, Inc.
131 Kelekent Lane
Cary, North Carolina 27511

Re: K003886
Trade Name: Palomar SpaLight™ Pulsed Light System
Regulatory Class: II
Product Code: GEX
Dated: December 14, 2000
Received: December 18, 2000

Dear Ms. Moore:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number: K003886

Device Name: SpaLight™

Indications for Use:

The SpaLight™ Pulsed Light system is intended to remove hair in Dermatology and Plastic Surgery procedures in all skin types (including Fitzpatrick's I-VI). It is also indicated for photocoagulation of dermatological vascular lesions, photothermolysis of blood vessels (treatment of facial and leg veins)

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use____
(per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003886